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March 13, 2015

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Honorable Jerome B. Simandle, Chief Judge
Honorable Karen M. Williams, U.S.M.J.
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
1 John F. Gerry Plaza
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Otsuka v. Mylan*, 14-cv-04508
Otsuka v. Zydus, 14-cv-3168 and 14-cv-7252
Otsuka v. Aurobindo, 14-cv-3306 and 14-cv-6890
Otsuka v. Apotex, 14-cv-08074
Otsuka v. Actavis Elizabeth, 14-cv-07106

Dear Chief Judge Simandle and Judge Williams,

We along with our co-counsel Alston & Bird LLP, represent Mylan in the above matter. We write on behalf of the defendants from the above-referenced pending actions (collectively, "Defendants") in opposition to the March 9, 2015 letter request from Melissa Chuderewicz, Esq., counsel for plaintiff Otsuka.

Plaintiff has again requested an *extraordinary* order directing Defendants to provide advance disclosure for the launch of a generic aripiprazole product, and seeking a briefing schedule relating thereto. As noted below, this Court has already rejected Otsuka's request, and Plaintiff offers no legal support for its renewed demand. In fact, Plaintiff fails to provide a single decision that has held that a generic pharmaceutical company has the legal obligation to provide such notice. That is not surprising as Defendants are not aware of any such decision.

Further, there is no need for a briefing schedule on this issue. Not just because the Court already rejected Otsuka's request, but also because there is no authority supporting the exercise of judicial power in these circumstances. To the contrary, every decision on this issue holds otherwise.

For the following reasons, we respectfully submit that Otsuka's renewed request should be denied:

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I. OTSUKA'S REQUEST HAS BEEN REJECTED BY THIS COURT

At the January 13, 2015 conference before Judge Williams, the Court decided that Defendants are not required to provide advance notice of a generic launch. The Court told Otsuka that it could make a motion if it wanted to convince the Court otherwise, but Otsuka chose not to do so. Not only is Otsuka's renewed request procedurally infirm, but as we demonstrate herein, the law is unanimously in support of Judge Williams' decision.

Moreover, the Court did not order any Defendant to give notice of launch plans. Rather, the Court stated that, if a Defendant *agreed* to give notice, such a Defendant should do so by February 23, 2015. ECF No. 45 at 7 in Civil Action No. 14-04508. Mylan did not agree to provide such notice and that date has come and gone. Plaintiff cannot now force Mylan to disclose its confidential launch plans, if any.

Inasmuch as this Court has already rejected Otsuka's request and in the face of the extant law supporting that rejection, there is no reason to revisit the notice of launch issue, and no reason to require any briefing.

II. THE LAW OVERWHELMINGLY SUPPORTS THIS COURT'S DECISION

Judge Esther Salas confirmed that product launch information "is indisputably confidential, sensitive business information" that is among the most highly confidential, competitive commercial information in a generic firm's possession. *See Hoffman-LaRoche, Inc. v. Teva Pharm. USA, et al.*, Civil Action No. 11-3635 (ES) (D.N.J. Feb. 5, 2013) ("*Roche*"), Letter Order, ECF No. 124 (*see* Exhibit 1) (declining to order disclosure of launch information). As Judge Salas found, "*Teva has no obligation to provide notice of its intent to launch its generic version,*" and rejected the assertion that "the Court has the authority to order advance notice of [Teva's] intent to launch in the absence of an agreement by Teva." *Roche*, Letter Order, ECF No. 124 (Emphasis added).

The importance of a product-launch decision to a generic pharmaceutical company and the business factors that enter into that decision are not only critical to a generic firm's ability to effectively compete against brand companies such as Plaintiff, but are equally critically important to the ability to compete *against other generic firms*. For example, if the Court were to require Mylan to disclose its launch decision, it is conceivable that Plaintiff would launch an authorized generic a few days before Mylan. This would be competitively damaging to Mylan and a trade secret windfall to Plaintiff. These issues involve the highest level corporate decision-making processes and demand the strictest levels of confidentiality.

For these reasons it is not surprising that there is *not a single case* supporting the exercise of federal judicial power to issue the order plaintiffs seek. *See Teva Pharm. USA, et al. v. Sandoz, et al.*, Civil Action No. 08-7611 (BSJ) (S.D.N.Y. Oct. 12, 2010)

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(“*Teva*”), Order, ECF No. 197 (*see* Exhibit 2) (declining to order advance notice and stating “*Defendants are under no legal obligation to provide Plaintiffs with notice of its intent and ability to launch. Plaintiffs’ request essentially amounts to a request for the Court to order Defendants to provide Plaintiffs with confidential business information, which, for all intent and purposes, would function as an injunction by prohibiting Defendants from launching their product even if they have FDA approval and the thirty-month statutory stay period has expired.*”) (Emphasis added).

The Judges in this District have rendered consistent decisions rejecting disclosure of launch plans: Judge Ackerman stated that “*Teva was under no obligation to provide such notice*” of its intended launch. *Novartis Corp. v. Teva Pharms. USA, Inc.*, Civ. Nos. 04-4473, 06-1130, 2007 WL 1695689, at *30 (D.N.J. June 11, 2007). Judge Lifland concluded, in connection with a preliminary injunction application, that he would not “go so far as to urge anyone to take any particular business action” as that was not the Court’s “place,” and further stating that “I am not going to impose any legal obligation on anyone to, as I said, adjust their business to what might be considered a nicety of court proceedings.” *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 00-02931, Tr. of Proceedings at 100-01 (Sept. 24, 2004) (*see* Exhibit 3). Judge Bumb found that “*AstraZeneca’s letter application, in which it sought to have the Court enter an order directing that Defendant Breath...be ordered to provide advance notice of any anticipated launch of, or any launch plans concerning, its [ANDA product] is denied for the reasons in the record of these proceedings, including because the Court does not believe it has legal authority to grant such relief.*” *AstraZeneca LP v. Breath, Ltd.*, No. 08-01512, ECF Document No. 86 at 3 (D.N.J. filed Sept. 8, 2009) (*see* Exhibit 4) (emphasis added); *see also* Aug. 12, 2009 Tr. of Hrg. at 8:6-13 (*see* Exhibit 5) (“*I don’t believe that I have the legal authority to order...them to provide such notice and so I’m not going to do it.*”) (Emphasis added). Magistrate Judge Bongiovanni denied a request for a 45 day advance notice of a planned commercial launch in *AstraZeneca LP v. Osmotica Pharms. Corp.*, No. 10-4203, ECF Document No. 42 at 2 (D.N.J. filed Nov. 16, 2010) (*see* Exhibit 6), and in a different case, Judge Bongiovanni stated that “I’ve been reluctant to and have refused to require that Mylan state when they would launch.” *Novartis Pharms. Corp. v. Mylan Pharms.*, No. 06-2885, Trans. of Tel. Conf. at 6 (D.N.J. Sept. 22, 2008) (*see* Exhibit 7); *see also* Judge Bumb’s conclusion that “*there is nothing*” the Court “*can do to force [the generic] to agree*” to provide advance notice. *AstraZeneca LP v. Ivax Pharms., Inc.*, No. 05-5142, Trans. of Teleconf. at 10 (D.N.J. July 17, 2008) (*see* Exhibit 8).

Instead of providing any legal support for its extraordinary request, Otsuka attempts to justify its application by arguing that a failure to provide such launch plans is “frustrating the orderly administration of these actions.” Mylan respectfully submits that even if that was true—which it is not—considerations of docket control and scheduling cannot trump the *fundamental question* of whether a federal court has judicial power to enter the order requested here.

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As Judge Lifland stated in *Purepac, supra*, “the nicety of court proceedings” cannot overcome the issue of whether a legal obligation exists to provide any notice of launch. Similarly, in *Teva, supra*, Judge Jones concluded that while “the Court appreciates Plaintiffs’ desire to avoid saddling the Court with an emergency and possibly unnecessary request for a temporary restraining order, the Court is confident” that Rule 65, Fed. R. Civ. P. “provides more than ample recourse” to Plaintiff. Judge Salas concurs:

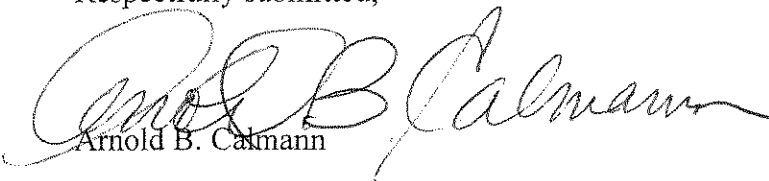
Although this Court recognizes that it has discretion to manage its docket, *the Court finds that Teva has no obligation to provide notice of its intent to launch its generic version of Xeloda® at risk – which is indisputably confidential, sensitive business information.... [T]he Court finds the Federal Rule of Civil Procedure 65 provides adequate recourse should Teva launch its generic product.*

(Emphasis added).

The importance of a generic firm’s highly protected and confidential decision to launch cannot be overcome by scheduling issues that have yet to materialize. It is understandable that the Court would be concerned about scheduling and wish to avoid unnecessary injunction proceedings if possible. However, we submit that those concerns cannot trump Mylan’s right to protect its confidential and proprietary information. Scheduling concerns cannot be the basis for Plaintiff to advocate for an expansion of judicial authority. As there is no legal basis to support Plaintiff’s application, it should be denied.¹

We respectfully submit that Otsuka’s application for relief should be rejected, and the unanimous federal decisions cited herein be followed. We thank the Court for its understanding and consideration in this matter.

Respectfully submitted,


Arnold B. Calmann

cc: Counsel of record (by CM/ECF)

¹ Even the Local Patent Rules, which are applicable to Hatch-Waxman litigations, do not provide any support for Plaintiff’s demand that Mylan provide notice of the existence of or details surrounding a commercial launch of a product.